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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/730,770	12/08/2003	Joost Dick de Bruijn	04148-00033	3424

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EXAMINER	
DUNSTON, JENNIFER ANN	
ART UNIT	**PAPER NUMBER**
1636	

DATE MAILED: 10/22/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/730,770	DE BRUIJN ET AL.	
	Examiner	Art Unit	
	Jennifer Dunston	1636	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 June 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-17* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-17* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *2/17/2004*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Receipt of a preliminary amendment, filed 12/8/2003, in which the specification was amended is acknowledged. Receipt of a preliminary amendment, filed 6/21/2004, in which the claims were amended is also acknowledged.

Claims 1-17 are pending in the instant application.

Oath/Declaration

Receipt of a properly executed declaration, filed 5/13/2004, is acknowledged.

Specification

The abstract of the disclosure is objected to because it contains legal phraseology (see line 3, "said sample"). Correction is required. See MPEP § 608.01(b).

The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed.

The following title is suggested: Predicting the capacity of a cell population to induce bone formation.

The use of the trademarks Sigma 104® (page 6, lines 7; page 10, line 20), FIX® (page 11, line 2), and PERM® (page 11, line 4) has been noted in this application. It should be capitalized wherever it appears and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

Claim Objections

Claim 16 is objected to because of the following informalities: the claim recites the use of "alpha-naphtol AS-B1 phosphate," which should be spelled alpha-naphtol AS-BI phosphate. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-10 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are drawn to a method of assaying a cell population *in vitro* for the response to an osteogenic stimulation factor using the degree of expression of a bone-specific protein as a metric. Thus, the rejected claims can be interpreted to encompass the quantification of any bone-specific protein of any vertebrate species. Further, there are no functional limitations of the

bone-specific protein. Therefore, the rejected claims encompass an enormous genus of bone-specific proteins.

To provide adequate written description and evidence of possession of a claimed genus, the specification must provide sufficient distinguishing identifying characteristics of the genus. The factors to be considered include disclosure of a complete or partial structure, physical and/or chemical properties, functional characteristics, structure/function correlation and any combination thereof. The specification discloses the use of alkaline phosphatase, osteocalcin, bone sialo protein, osteopontin, and osteonectin (e.g. page 5, lines 1-5). This group comprises enzyme and matrix proteins. Examples of assays for the detection alkaline phosphatase and osteocalcin are disclosed in the specification. No description is provided of any other bone-specific proteins. Further, the specification does not identify any distinguishing characteristics of the genus.

Even if one accepts that the examples described in the specification meet the claim limitations of the rejected claims with regard to bone-specific expression, the examples are only representative of known markers of osteogenesis. The results described are not necessarily predictive of the set of bone-specific proteins of any vertebrate species. For example, a protein may be isolated from bone tissue or osteoblasts, yet one would not necessarily know whether this protein is a bone-specific protein without first testing various tissues at different developmental stages. Further, to determine if the protein is a marker of osteoblast differentiation, one would need to study the expression of the protein during osteogenesis to confirm that the expression of the protein is regulated during differentiation of precursor cells to form osteoblasts, making it impossible for one to extrapolate from the few bone-specific protein described herein those

promoter sets that would necessarily meet the functional/structural characteristics of the rejected claims.

The prior art does not appear to offset the deficiencies of the instant specification in that it does not provide a reliable structural/functional basis for one of skill in the art to envision the proteins, nucleic acid coding sequences or genes that necessarily meet the limitation of a bone-specific protein.

There is no structural/functional basis provided by the prior art or instant specification for one of skill in the art to envision the set of bone-specific proteins from any vertebrate species. Therefore, one of skill in the art would not have been able to envision a representative number of bone-specific proteins to describe the broad genus encompassed by the rejected claims. One of skill in the art would thus have reasonably concluded applicants were not in possession of the claimed invention for claims 1-10.

Claim 13 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Claim 13 is drawn to the use of the anti-ALP antibody of hybridoma B4-78.

The application discloses hybridoma B4-78 that is encompassed by the definitions for **biological material** set forth in 37 C.F.R. § 1.801. Because it is apparent that this biological material is essential for practicing the claimed invention, it must be obtainable by a reproducible

method set forth in the specification or otherwise be known and readily available to the public as detailed in 37 C.F.R. §§ 1.801 through 1.809.

It is unclear whether this biological material is known and readily available to the public or that the written instructions are sufficient to reproducibly construct this biological material from starting materials known and readily available to the public. Accordingly, availability of such biological material is deemed necessary to satisfy the enablement provisions of 35 U.S.C. § 112. If this biological material is not obtainable or available, the requirements of 35 U.S.C. § 112 may be satisfied by a deposit of the biological material. In order for a deposit to meet all criteria set forth in 37 C.F.R. §§ 1.801-1.809, applicants or assignee must provide assurance of compliance with provisions of 37 C.F.R. §§ 1.801-1.809, in the form of a declaration or applicant's representative must provide a statement. The content of such a declaration or statement is suggested by the enclosed attachment. Because such deposit will not have been made prior to the effective filing date of the instant application, applicant is required to submit a verified statement from a person in a position to corroborate the fact, which states that the biological material which has been deposited is the biological material specifically identified in the application as filed (37 C.F.R. § 1.804). Such a statement need not be verified if the person is an agent or attorney registered to practice before the Office. Applicant is also reminded that the specification must contain reference to the deposit, including deposit (accession) number, date of deposit, name and address of the depository, and the complete taxonomic description. A statement that all restrictions on the availability to the public of the material so deposited will be irrevocably removed upon granting of a patent is also required.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-17 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1, 11 and 12 are vague and indefinite in that the metes and bounds of the term "bone-specific protein" are unclear. The term is unclear in that the it can be interpreted to mean a protein that is exclusively expressed in bone and is not expressed in any other tissue at any time in development. Alternatively, it could be interpreted to mean a protein that is a marker for osteoblast differentiation. It would be remedial to amend the claim to indicate that the protein is a marker for osteoblast differentiation or is a bone-associated or bone-related protein, for example.

The term "based on α-MEM" in claim 7 is a relative term which renders the claim indefinite. The term "based on α-MEM " is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. The term "based on α-MEM" is unclear in that one of ordinary skill in the art would not know how much one could vary the composition of the medium in terms of the quantity of inorganic salts, amino acids, vitamins, sugars or pH, for example, and meet the limitations of the claimed invention.

Claim 7 is vague and indefinite in that the metes and bounds of the phrase "wherein the medium further comprises L-ascorbic acid 2-phosphate, an antibiotic serum, and/or a growth factor" are unclear. The phrase is unclear in that the phrase can be interpreted as a medium containing any combination of one or more of the components listed. Alternatively, the phrase can be interpreted as a medium that contains three components (L-ascorbic acid 2-phosphate, an antibiotic and serum) with or without the addition of a growth factor. Alternatively, the phrase can be interpreted as a medium that contains three components (L-ascorbic acid 2-phosphate, an antibiotic and serum) or contains a growth factor. It would be remedial to amend the claim to clearly identify the combination of components that the medium must contain.

Regarding claim16, the phrase "preferably" renders the claim indefinite because it is unclear whether the limitations following the phrase are part of the claimed invention. See MPEP § 2173.05(d).

Claim 17 contains the trademark/trade name Sigma 104® phosphate substrate. Where a trademark or trade name is used in a claim as a limitation to identify or describe a particular material or product, the claim does not comply with the requirements of 35 U.S.C. 112, second paragraph. See *Ex parte Simpson*, 218 USPQ 1020 (Bd. App. 1982). The claim scope is uncertain since the trademark or trade name cannot be used properly to identify any particular material or product. A trademark or trade name is used to identify a source of goods, and not the goods themselves. Thus, a trademark or trade name does not identify or describe the goods associated with the trademark or trade name. In the present case, the trademark/trade name is

used to identify/describe para-nitrophenyl phosphate (pNPP) disodium hexahydrate and, accordingly, the identification/description is indefinite.

Claim 17 is vague and indefinite in that the metes and bounds of the phrase "and the reaction product is reacted further with Sigma 104® phosphatase substrate and subsequently detected by UV" is unclear. Sigma 104® phosphatase substrate is a trade name for para-nitrophenyl phosphate, however, the claim recites the use of para-nitro phenyl phosphate in addition to Sigma 104® phosphatase substrate. It is not clear whether the Sigma 104® phosphatase substrate has properties not found in the generic compound, para-nitrophenyl phosphate, or whether the generic compound could be used alone. It would be remedial to amend the claim to either remove the recitation of Sigma 104® phosphatase substrate or clarify why this compound must be used.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 4, 5, 7, 8, 10-13 and 14 are rejected under 35 U.S.C. 102(b) as being anticipated by Walsh et al (Bone, Vol. 27, No. 2, pages 185-195, 2000) as evidenced by Cheng et al (Endocrinology, Vol. 134, No. 1, pages 277-286, 1994).

Walsh et al teach a method of determining the osteogenic potential of a population of cultured cells (e.g. paragraph bridging pages 192-193). Human bone marrow cells are obtained from patients undergoing thoracic surgery (e.g. page 186, *Subjects*). Cells are seeded at a density of 2×10^4 cells/cm^2 and cultured in standard medium consisting of Hepes-buffered Dulbecco's modified Eagle's medium (DMEM) supplemented with fetal calf serum, L-glutamine, penicillin, streptomycin, and L-ascorbic acid 2-phosphate (e.g. page 186, *Culture of human BMSCs*). The cells are cultured in the presence or absence of 10 nmol/L (10^{-8} M) dexamethasone (Dx) in standard medium (e.g. page 186, *Culture of human BMSCs*). Further, the cells are cultured in standard medium the presence or absence of FGF-2, a growth factor and an osteogenic stimulation factor (e.g. page 186, *Culture of human BMSCs*; paragraph bridging pages 189-190). Following the growth of cells, the alkaline phosphatase (AP) activity was determined using para-nitrophenyl phosphate (see Cheng et al, page 278, *Alkaline phosphatase assay* for assay conditions) and the following comparisons can be made: (i) cells grown in standard medium and cells grown in standard medium plus FGF-2 (e.g. page 186, *Cell Counting and Determination of AP Activity*; Figure 1), (ii) cells grown in standard medium and cells grown in standard medium plus Dx (e.g. Figure 2), (iii) cells grown in the standard medium plus FGF-2 in the presence or absence of Dx (e.g. Figure 2). Moreover, the anti-alkaline phosphatase monoclonal antibody from Hybridoma B4-78 is used for flow-cytometric analysis of cells grown in the standard medium, standard medium plus Dx, standard medium plus FGF-2, and standard medium plus Dx and FGF-2, where the presence of alkaline phosphatase indicates the presence of osteoprogenitor cells and maturing osteoblasts in the sample (e.g. page 186, *Antibodies*; Figure 4; Figure 5; page 190, paragraph bridging the left and right columns).

Claims 1-5, 7, 8, 10, 11, and 14-17 are rejected under 35 U.S.C. 102(b) as being anticipated by Scheven et al (Journal of Bone and Mineral Research, Vol. 10, No. 6, pages 874-880, 1995; see the entire reference).

Scheven et al teach the establishment of human osteoblast cultures from trabecular bone explants of femoral heads obtained from orthopedic surgery (total hip replacement) patients (e.g. page 875, *Osteoblast cell culture and experimental set-up*). Explants are cultured in α-minimal essential medium (α-MEM) containing fetal bovine serum (FBS), glutamine and antibiotics (streptomycin, penicillin, and fungizone) (e.g. 875, *Osteoblast cell culture and experimental set-up*). Further, equal numbers of cells are cultured in the presence or absence of $1,25(OH)_2D_3$ (vitamin D3) used at a concentration range from 10^{-10} to 10^{-5} M (e.g. page 875, *Osteoblast cell culture and experimental set-up*). The osteoblast differentiation parameters of cells grown in the presence and absence of vitamin D3 are compared using the following assays: (i) cellular alkaline phosphatase is assessed cytochemically using Naphtol AS-BI phosphate as a substrate and Fast Blue BB as a coupler, (ii) alkaline phosphatase activity is measured by incubating the cells in a solution containing p-nitrophenyl phosphate and quantifying the production of p-nitrophenol by measuring the absorbance at 405 nm, and (iii) osteocalcin is determined in culture medium (e.g. page 875, *Osteoblast differentiation parameters*; Table 1; Figure 2).

Claims 1-5 and 7-11 are rejected under 35 U.S.C. 102(b) as being anticipated by Locklin et al (Cell Biology International, Vol. 23, No. 3, pages 185-194, 1999; see the entire reference).

Locklin et al teach the isolation of primary cultures of bone marrow cells obtained from patients undergoing total hip replacement surgery and the growth of the cultures in alpha-minimum essential medium containing fetal calf serum, penicillin and streptomycin (e.g. page 186, *Cell culture*). For the long-term growth of cells, 1 x 10^4 cells and grown under the following conditions: (i) without the addition of bFGF or Dex, (ii) in the presence of bFGF, (iii) in the presence of Dex Dex (Dexamethasone, 10^{-8} M), and (iv) in the presence of bFGF and Dex (e.g. page 187, left column; Table 1). After culture for 11 days, the alkaline phosphatase activity of the resulting colony forming units is determined and compared between groups (e.g. Table1; pages 189-190, bridging paragraph).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claim 11 is rejected under 35 U.S.C. 103(a) as being unpatentable over Walsh et al in view of Nefussi et al (The Journal of Histochemistry & Cytochemistry, Vol. 45, No. 4, pages 493-503, 1997; see the entire reference).

The teachings of the Walsh et al reference are described above and are applied as before, except:

Walsh et al teach a method of determining the osteogenic potential of a population of cultured cells using a monoclonal antibody to alkaline phosphatase to quantify osteoprogenitor cells and maturing osteoblasts in the sample. Walsh et al do not teach the quantification of bone sialo protein or osteonectin expression.

Nefussi et al teach the isolation of rat calvaria bone cells, which are seeded at 2×10^4 cells in Dulbecco's modified Eagle's medium with fetal calf serum, streptomycin, and penicillin (e.g. page 494, Bone Cell Isolation and Culture). After 15 days, the cells are fixed and sectioned for detection of bone sialo protein (BSP) and osteonectin (ON) using an EM immunohistochemical procedure (e.g. page 494, EM Immunohistochemical procedure; Figure 1). Further, Nefussi et al teach the association of BSP and ON with the osteoid and the mineralized matrix formed by the cultured cells in a manner that duplicates what is observed during osteogenesis *in vivo* (e.g. Abstract; page 501, left column, last paragraph).

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the teachings of Walsh et al to include the antibodies and detection methods taught by Nefussi et al because Walsh et al teach it is within the skill of the art to use antibodies to detect markers of osteogenic differentiation and because Nefussi et al teach the use of antibodies to

detect the mineralized matrix formed by the cultured cells. The skilled artisan would have been motivated to make such a modification in order to receive the expected benefit of observing a phenotype *in vitro* that is an indicator of bone formation observed *in vivo*. Absent any evidence to the contrary, there would have been a reasonable expectation of success in modifying the teachings of Walsh et al to include the detection of BSP and ON as taught by Nefussi et al.

Claim 11 is rejected under 35 U.S.C. 103(a) as being unpatentable over Walsh et al in view of Candeliere et al (Bone, Vol. 28, No. 4, pages 351-361, 2001).

The teachings of the Walsh et al reference are described above and are applied as before, except:

Walsh et al teach a method of determining the osteogenic potential of a population of cultured cells using a monoclonal antibody to alkaline phosphatase to quantify osteoprogenitor cells and maturing osteoblasts in the sample. Walsh et al do not teach the quantification of bone sialo protein, osteocalcin, and osteopontin.

Candeliere et al teach the use of antibodies directed against alkaline phosphatase (ALP), bone sialo protein (BSP), osteocalcin (OCN) and osteopontin (OPN) to determine the expression pattern of each protein in sections of neonatal rat calvarial bone (e.g. page 352, left column, last full paragraph; pages 352-353, *Immunohistochemistry*). Further, Candeliere teach that all osteoblasts and preosteoblasts express ALP (e.g. paragraph bridging pages 353-354). Moreover, Candeliere et al teach the differential expression of BSP, OCN and OPN demonstrating that different subsets of preosteoblasts, osteoblasts and osteocytes express diverse gene profiles depending on their position within the developing clavaria (e.g. Tables 1, 2 and 3).

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the teachings of Walsh et al to include the antibodies taught by Candeliere et al because Walsh et al teach it is within the skill of the art to use antibodies to detect markers of osteogenic differentiation and because Candeliere et al teach the use of antibodies to further characterizing the cells of the osteoblast lineage. The skilled artisan would have been motivated to make such a modification in order to receive the expected benefit of further characterizing cells differentiated *in vitro*. Absent any evidence to the contrary, there would have been a reasonable expectation of success in modifying the teachings of Walsh et al to include the detection of BSP, OCN and OPN as taught by Candeliere et al.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jennifer Dunston whose telephone number is 571-272-2916. The examiner can normally be reached on M-F, 9 am to 5 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel can be reached on 571-272-0781. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR, http://pair-direct.uspto.gov) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your

application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

Jennifer Dunston
Examiner
Art Unit 1636

jad

GERRY LEFFERS
PRIMARY EXAMINER

SUGGESTION FOR DEPOSIT OF BIOLOGICAL MATERIAL

A declaration by applicant or assignee, or a statement by applicant's agent identifying a deposit of biological material and averring the following may be sufficient to overcome an objection or rejection based on a lack of availability of biological material. Such a declaration:

1. Identifies declarant.

2. States that a deposit of the material has been made in a depository affording permanence of the deposit and ready accessibility thereto by the public if a patent is granted. The depository is to be identified by name and address. (See 37 C.F.R. § 1.803).

3. States that the deposited material has been accorded a specific (recited) accession number.

4. States that all restrictions on the availability to the public of the material so deposited will be irrevocably removed upon the granting of the patent. (See 37 C.F.R. § 1.808(a)(2)).

5. States that the material has been deposited under conditions that assure that access to the material will be available during the pendency of the patent application to one determined by the Commissioner to be entitled thereto under 37 C.F.R. § 1.14 and 35 U.S.C. § 122. (See 37 C.F.R. § 1.808(a)(1)).

6. States that the deposited material will be maintained with all the care necessary to keep it viable and uncontaminated for a period of at least five years after the most recent request for the furnishing of a sample of the deposited microorganism, and in any case, for a period of at least thirty (30) years after the date of deposit or for the enforceable life of the patent, whichever period is longer. See 37 C.F.R. § 1.806).

7. That he/she declares further that all statements made therein of his/her own knowledge are true and that all statements made on information and belief are believed to be true; and further, that these statements were made with knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the instant patent application or any patent issuing thereon.

Alternatively, it may be averred that deposited material has been accepted for deposit under the Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure (e.g., see 961 OG 21, 1977) and that all restrictions on the availability to the public of the material so deposited will be irrevocably removed upon the granting of a patent.

Additionally, the deposit must be referred to in the body of the specification and be identified by deposit (accession) number, date of deposit, name and address of the depository, and the complete taxonomic description.